HIPAA and the State of Utah, Department of Health, Newborn Screening

Limits on Use of Personal Medical Information.
The privacy rule sets limits on how health plans and covered providers may use individually identifiable health information. To promote the best quality care for patients, the rule does not restrict the ability of doctors, nurses and other providers to share information needed to treat their patients. In other situations, though, personal health information generally may not be used for purposes not related to health care, and covered entities may use or share only the minimum amount of protected information needed for a particular purpose. In addition, patients would have to sign a specific authorization before a covered entity could release their medical information to a life insurer, a bank, a marketing firm or another outside business for purposes not related to their health care.

Public Responsibilities.
In limited circumstances, the final rule permits -- but does not require --covered entities to continue certain existing disclosures of health information for specific public responsibilities. These permitted disclosures include: emergency circumstances; identification of the body of a deceased person, or the cause of death; public health needs; research that involves limited data or has been independently approved by an Institutional Review Board or privacy board; oversight of the health care system; judicial and administrative proceedings; limited law enforcement activities; and activities related to national defense and security. The privacy rule generally establishes new safeguards and limits on these disclosures. Where no other law requires disclosures in these situations, covered entities may continue to use their professional judgment to decide whether to make such disclosures based on their own policies and ethical principles.

Permitted PHI Disclosures Without Authorization
The Privacy Rule permits a covered entity to use and disclose PHI, with certain limits and protections, for TPO activities [45 CFR § 164.506]. Certain other permitted uses and disclosures for which authorization is not required follow. Additional requirements and conditions apply to these disclosures. The Privacy Rule text and OCR guidance should be consulted for a full understanding of the following:
Required by law. Disclosures of PHI are permitted when required by other laws, whether federal, tribal, state, or local.

Public health. PHI can be disclosed to public health authorities and their authorized agents for public health purposes including but not limited to public health surveillance, investigations, and interventions.

Health research. A covered entity can use or disclose PHI for research without authorization under certain conditions, including 1) if it obtains documentation of a waiver from an institutional review board (IRB) or a privacy board, according to a series of considerations; 2) for activities preparatory to research; and 3) for research on a decedent's information.

Abuse, neglect, or domestic violence. PHI may be disclosed to report abuse, neglect, or domestic violence under specified circumstances.
Law enforcement. Covered entities may, under specified conditions, disclose PHI to law enforcement officials pursuant to a court order, subpoena, or other legal order, to help identify and locate a suspect, fugitive, or missing person; to provide information related to a victim of a crime or a death that may have resulted from a crime, or to report a crime.
Judicial and administrative proceedings. A covered entity may disclose PHI in the course of a judicial or administrative proceeding under specified circumstances.
Cadaveric organ, eye, or tissue donation purposes. Organ-procurement agencies may use PHI for the purposes of facilitating transplant.

Oversight. Covered entities may usually disclose PHI to a health oversight agency for oversight activities authorized by law.

Worker's compensation. The Privacy Rule permits disclosure of work-related health information as authorized by, and to the extent necessary to comply with, workers' compensation programs.

Other Authorized Disclosures

A valid authorization is required for any use or disclosure of PHI that is not required or otherwise permitted without authorization by the Privacy Rule. In general, these authorizations must specifically identify the PHI to be used or disclosed;
provide the names of persons or organizations, or classes of persons or organizations, who will receive, use, or disclose the PHI; state the purpose for each request;
notify individuals of their right to refuse to sign the authorization without negative consequences to treatment, payment, or health plan enrollment or benefit eligibility, except under specific circumstances; be signed and dated by the individual or the individual's personal representative; be written in plain language; include an expiration date or event; notify the individual of the right to revoke authorization at any time in writing, and how to exercise that right, and any applicable exceptions to that right under the Privacy Rule; and explain the potential for the information to be subject to redisclosure by recipient and no longer protected by the Privacy Rule.

The Privacy Rule and Public Health

The Privacy Rule recognizes 1) the legitimate need for public health authorities and others responsible for ensuring the public's health and safety to have access to PHI to conduct their missions; and 2) the importance of public health reporting by covered entities to identify threats to the public and individuals. Accordingly, the rule 1) permits PHI disclosures without a written patient authorization for specified public health purposes to public health authorities legally authorized to collect and receive the information for such purposes, and 2) permits disclosures that are required by state and local public health or other laws. However, because the Privacy Rule affects the traditional ways PHI is used and exchanged among covered entities (e.g., doctors, hospitals, and health insurers), it can affect public health practice and research in multiple ways. To prevent misconceptions, understanding the Privacy Rule is important for public health practice. Some illustrative examples are presented in this report (Box 4). Also provided are sample letters that might prove useful in clarifying relationships involving public health and the Privacy Rule (Appendix B).

A public health authority is broadly defined as including agencies or authorities of the United States, states, territories, political subdivisions of states or territories, American Indian tribes, or an individual or entity acting under a grant of authority from such agencies and responsible for public health matters as part of an official mandate. Public health authorities include federal public health agencies (e.g., CDC, National Institutes of Health [NIH], Health Resources and Services Administration [HRSA], Substance Abuse and Mental Health Services Administration [SAMHSA], Food and Drug Administration [FDA], or Occupational Safety and Health Administration [OSHA]); tribal health agencies; state public health agencies (e.g., public health departments or divisions, state cancer registries, and vital statistics departments); local public health agencies; and anyone performing public health functions under a grant of authority from a public health agency [45 CFR § 164.501].

Public health agencies often conduct their authorized public health activities with other entities by using different mechanisms (e.g., contracts and memoranda or letters of agreement). These other entities are public health authorities under the Privacy Rule with respect to the activities they conduct under a grant of authority from such a public health agency. A covered entity may disclose PHI to public health authorities and to these designated entities pursuant to the public health provisions of the Privacy Rule.
The Privacy Rule permits covered entities to disclose PHI, without authorization, to public health authorities or other entities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This includes the reporting of disease or injury; reporting vital events (e.g., births or deaths); conducting public health surveillance, investigations, or interventions; reporting child abuse and neglect; and monitoring adverse outcomes related to food (including dietary supplements), drugs, biological products, and medical devices [45 CFR 164.512(b)]. Covered entities may report adverse events related to FDA-regulated products or activities to public agencies and private entities that are subject to FDA jurisdiction [45 CFR 164.512(b)(1)(iii)]. To protect the health of the public, public health authorities might need to obtain information related to the individuals affected by a disease. In certain cases, they might need to contact those affected to determine the cause of the disease to allow for actions to prevent further illness. Also, covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority [45 CFR 164.512(b)(1)(i)].

To receive PHI for public health purposes, public health authorities should be prepared to verify their status and identity as public health authorities under the Privacy Rule. To verify its identity, an agency could provide any one of the following:

if the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;
if the request is in writing, the request is on the appropriate government letterhead;
if the disclosure is to a person acting on behalf of a public health authority, a written statement on appropriate government letterhead that the person is acting under the government's authority [45 CFR § 164.514(h)(2)].

Public health authorities receiving information from covered entities as required or authorized by law [45 CFR 164.512(a)] [45 CFR 164.512(b)] are not business associates of the covered entities and therefore are not required to enter into business associate agreements. Public health authorities that are not covered entities also are not required to enter into business associate agreements with their public health partners and contractors. Also, after PHI is disclosed to a public health authority pursuant to the Privacy Rule, the public health authority (if it is not a covered entity) may maintain, use, and disclose the data consistent with the laws, regulations, and policies applicable to the public health authority.

Disclosures for Public Health Purposes
The Privacy Rule allows covered entities to disclose PHI to public health authorities when required by federal, tribal, state, or local laws [45 CFR 164.512(a)]. This includes state laws (or state procedures established under such law) that provide for receiving reporting of disease or injury, child abuse, birth, or death, or conducting public health surveillance, investigation, or intervention.
For disclosures not required by law, covered entities may still disclose, without authorization, to a public health authority authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, the minimum necessary information to accomplish the intended public health purpose of the disclosure [45 CFR 164.512 (b)] (Box 1).

For example, to protect the health of the public, public health officials might need to obtain information related to persons affected by a disease. In certain cases, they might need to contact those affected to determine the cause of the disease to allow for actions to prevent further illness. The Privacy Rule continues to allow for the existing practice of sharing PHI with public health authorities who are authorized by law to collect or receive such information to aid them in their mission of protecting the health of the public. Examples of such activities include those directed at the reporting of disease or injury, reporting adverse events, reporting births and deaths, and investigating the occurrence and cause of injury and disease (*1*).

Although it is not a defined term, DHHS interpreted the phrase "authorized by law" to mean that a legal basis exists for the activity. Further, DHHS called the phrase "a term of art," including both actions that are permitted and actions that are required by law [64 FR 59929, November 3, 1999]. This does not mean a public health authority at the federal, tribal, state, or local level must have multiple disease or condition-specific laws that authorize each collection of information. Public health authorities operate under broad mandates to protect the health of their constituent populations.